UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/245,198	02/05/99	BROWNING J	A003

HM12/0414

BIOGEN INC
14 CAMBRIDGE CENTER
CAMBRIDGE MA 02142

EXAMINER	
KERR,J	
ART UNIT	**PAPER NUMBER**
1633	7

DATE MAILED: 04/14/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/245,198	Applic(s) Chicheportiche et al.
	Examiner Janet M. Kerr	Group Art Unit 1633

☒ Responsive to communication(s) filed on *Feb 5, 1999* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *one* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-35* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-35* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 26, and 28-31 drawn to polynucleotides, vectors and host cells comprising the polynucleotides, and methods of using polynucleotides, classified in class 435, subclasses 69.1, 70.1, 320.1, class 514, subclass 44, and class 536, subclasses 23.1 and 23.5, for example.

II. Claims 11-13, 15, 21, and 22, drawn to polypeptides, classified in class 530, subclass 350, for example.

III. Claims 14, 17, and 18, drawn to a method for preventing or reducing the severity of autoimmune disease by administering a polypeptide, classified in class 514, subclasses 2 and 885, for example.

IV. Claim 16, drawn to a method for preventing or reducing the severity of an immune response to a tissue graft by administering a polypeptide, classified in class 424, subclass 520, and class 514, subclasses 2 and 885, for example.

V. Claim 19, drawn to a method for treating cancer by administering a polypeptide, classified in class 514, subclass 2, for example.

VI. Claim 20, drawn to a method for identifying a receptor, classified in class 435, subclass 7.1, for example.

VII. Claims 23-25, and 27, drawn to antibodies and methods of use, classified in class 424, subclass 130.1, and class 530, subclass 387.1, for example.

VIII. Claims 32-33, drawn to a method of inducing cell death, classified in class 514, subclass 2, and class 530, subclass 350, for example.

IX. Claims 34-35, drawn to a method of treating, suppressing or altering an immune response involving a signaling pathway between TRELL and its receptor, classified in class 514, subclasses 2 and 885, and class 530, subclass 350, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, and VII are distinct, each from the other, as the inventions are directed to materially different products with different chemical structures and different functions. In addition, the polynucleotides, polypeptides, and antibodies of Inventions I, II, and VII, respectively can be used in materially different processes. For example, polynucleotides can be used as hybridization probes, polypeptides can be used for antigen presenting cell priming and antibodies can be used in polypeptide isolation protocols. The differences between Inventions I, II, and VII are further underscored by their divergent classification and independent search status.

Invention I is distinct from Inventions III-VI as the polynucleotides of Invention I are not required to reduce to practice the method of Invention III, directed to a method for preventing or reducing the severity of autoimmune disease by administering a polypeptide, the method of Invention IV, directed to preventing or reducing the severity of an immune response to a tissue graft by administering a polypeptide, the method of Invention V, directed to treating cancer by administering a polypeptide, or the method of Invention VI, directed to a method for identifying a receptor using a polypeptide, as the polypeptides required for reducing to practice Inventions III-VI can be obtained by means other than recombinant technology. For example, the polypeptides required for Inventions III-VI can be isolated from tissues or cells that endogenously express the polypeptide. In addition, the polynucleotides can be used in a materially different process such as using the polynucleotides as hybridization probes. The differences between Invention I and Inventions III-VI are further underscored by their divergent classification and independent search status.

Invention I is distinct from Inventions VIII and IX as the polynucleotides of Invention I are not required to reduce to practice the method of Invention VIII, directed to inducing cell death comprising administering an agent, or the method of Invention IX, directed to treating, suppressing, or altering an immune response involving a signaling pathway between TRELL and its receptor comprising administering an agent, as the agents required for reducing to practice Inventions VIII and IX are distinct structurally and functionally from the polynucleotides of Invention I. In addition, the polynucleotides can be used in a materially different process such as

using the polynucleotides as hybridization probes. The differences between Invention I and Inventions VIII and IX are further underscored by their divergent classification and independent search status.

Inventions II and III-VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Invention II can be used in a materially different process of using that product. For example, the polypeptides of Invention II can be used for antigen presenting cell priming. The differences between Invention II and Inventions III-VI are further underscored by their divergent classification and independent search status.

Invention II is distinct from Inventions VIII and IX as the polypeptides of Invention II are not required to reduce to practice the method of Invention VIII, directed to inducing cell death comprising administering an agent, or the method of Invention IX, directed to treating, suppressing, or altering an immune response involving a signaling pathway between TRELL and its receptor comprising administering an agent, as the agents required for reducing to practice Inventions VIII and IX are distinct structurally and functionally from the polypeptides of Invention II. In addition, the polypeptides can be used in a materially different process, such as for antigen presenting cell priming. The differences between Invention II and Inventions VIII and IX are further underscored by their divergent classification and independent search status.

Invention III is distinct from Inventions IV-VI as the method of Invention III, directed to preventing or reducing the severity of autoimmune disease requires different assays and different technical considerations, such as routes of administration and analytical protocols to determine the efficacy of the method, than those required for Invention IV, directed to preventing or reducing the severity of an immune response to a tissue graft, or Invention V, directed to treating cancer,

or those required for Invention VI, directed to identifying a receptor. The differences between Invention III and Inventions IV-VI are further underscored by their divergent classification and independent search status.

Invention III is distinct from Invention VII as the method of Invention III, directed to preventing or reducing the severity of autoimmune disease, does not require to reduce to practice the antibodies of Invention VII. Moreover, the antibodies of Invention VII can be used in a materially different process, i.e., for isolating and purifying polypeptides, for example. The differences between Invention III and Invention VII are further underscored by their divergent classification and independent search status.

Invention III is distinct from Inventions VIII and IX as the method of Invention III, directed to preventing or reducing the severity of autoimmune disease requires different reagents, different assays, and different technical considerations than the method of Invention VIII, directed to a method of inducing cell death, or the method of Invention IX, directed to a method of treating, suppressing, or altering an immune response involving a signaling pathway between TRELL and its receptor. For example, the polypeptides required to reduce to practice the method of Invention III are distinct structurally and functionally from the agents required to reduce to practice the methods of Inventions VIII and IX. The differences between Invention III and Inventions VIII and IX are further underscored by their divergent classification and independent search status.

Invention IV is distinct from Inventions V and VI as the method of Invention IV, directed to preventing or reducing the severity of an immune response to a tissue graft, requires different analytical techniques and different technical considerations than those required to reduce to practice the method of Invention V, directed to treating cancer, or those required in the method of Invention VI, directed to identifying a receptor. For example, the analytical protocols required to determine the impact of administering a polypeptide on a tissue graft-mediated immune response would not be the same as those required to determine the impact of administering a polypeptide

on cancer progression, nor would they be the same as those required to determine receptor-ligand binding activity. The differences between Invention IV and Inventions V and VI are further underscored by their divergent classification and independent search status.

Invention IV is distinct from Invention VII as the method of Invention IV, directed to preventing or reducing the severity of an immune response to a tissue graft, does not require to reduce to practice the antibodies of Invention VII. In addition, the antibodies of Invention VII can be used in a materially different process, e.g., for isolating and purifying polypeptides. The differences between Invention IV and Invention VII are further underscored by their divergent classification and independent search status.

Invention IV is distinct from Inventions VIII and IX as the method of Invention IV, directed to preventing or reducing the severity of an immune response to a tissue graft, requires different reagents, different analytical protocols, and different technical considerations than those required for the method of Invention VIII, directed to a method of inducing cell death, or Invention IX, directed to a method of treating, suppressing, or altering an immune response involving a signaling pathway between TRELL and its receptor. For example, the polypeptide required in the method of Invention IV is distinct structurally and functionally from the agents required in the methods of Inventions VIII and IX. The differences between Invention IV and Inventions VIII and IX are further underscored by their divergent classification and independent search status.

Invention V is distinct from Invention VI as the method of Invention V, directed to treating cancer, requires different analytical techniques and different technical considerations than those required to reduce to practice the method of Invention VI, directed to identifying a receptor. For example, the analytical protocols required to determine the impact of administering a polypeptide on cancer progression would not be the same as those required to determine receptor-ligand binding activity. The differences between Invention V and Invention VI are further underscored by their divergent classification and independent search status.

Invention V is distinct from Invention VII as the method of Invention IV, directed to treating cancer, does not require, to reduce to practice, the antibodies of Invention VII. In addition, the antibodies of Invention VII can be used in a materially different process, e.g., for isolating and purifying polypeptides. The differences between Invention V and Invention VII are further underscored by their divergent classification and independent search status.

Invention V is distinct from Inventions VIII and IX as the method of Invention V, directed to treating cancer, requires different reagents, different analytical protocols, and different technical considerations than those required for the method of Invention VIII, directed to a method of inducing cell death, or Invention IX, directed to a method of treating, suppressing, or altering an immune response involving a signaling pathway between TRELL and its receptor. For example, the polypeptide required in the method of Invention V is distinct structurally and functionally from the agents required in the methods of Inventions VIII and IX. The differences between Invention IV and Inventions VII and VIII are further underscored by their divergent classification and independent search status.

Invention VI is distinct from Invention VII as the method of Invention VI, directed to identifying a receptor, does not require to reduce to practice the method of Invention VII, directed to antibodies. In addition, the antibodies of Invention VII can be used in a materially different process, e.g., for isolating and purifying polypeptides. The differences between Invention VI and Invention VII are further underscored by their divergent classification and independent search status.

Invention VI is distinct from Inventions VIII and IX as the method of Invention VI, directed to identifying a receptor, requires different reagents, analytical steps, and technical considerations than those required to reduce to practice the method of Invention VIII, directed to inducing cell death, or the method of Invention IX, directed to a method of treating, suppressing, or altering an immune response involving a signaling pathway between TRELL and its receptor. For example, the polypeptides required to reduce to practice the method of Invention VI are

distinct structurally and functionally from the agents required to reduce to practice the methods of Inventions VIII and IX. The differences between Invention VI and Inventions VIII and IX are further underscored by their divergent classification and independent search status.

Invention VII is distinct from Inventions VIII and IX as the antibodies of Invention VII are not required to reduce to practice the method of Invention VIII, directed to inducing cell death, or the method of Invention IX, directed to a method of treating, suppressing, or altering an immune response involving a signaling pathway between TRELL and its receptor as the agents required in the methods of Inventions VIII and IX are distinct both structurally and functionally from the antibodies of Invention VII. In addition, the antibodies of Invention VII can be used in a materially different process, e.g., for isolating and purifying polypeptides. The differences between Invention VII and Inventions VIII and IX are further underscored by their divergent classification and independent search status.

Invention VIII is distinct from Invention IX as the method of inducing cell death of Invention VIII requires different analytical protocols and different technical considerations than the method of Invention IX, directed to a method of treating, suppressing, or altering an immune response involving a signaling pathway between TRELL and its receptor. For example, the analytical protocols required to determine the impact of administering an agent on cancer progression would not be the same as those required to determine the effect of an agent on an immune response. The differences between Invention VIII and Invention IX are further underscored by their divergent classification and independent search status.

The several inventions above are distinct from each other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not coextensive particularly with regard to the literature

search. Further, a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet M. Kerr whose telephone number is (703) 305-4055. Should the examiner be unavailable, inquiries should be directed to John LeGuyader, Supervisory Primary

Examiner of Art Unit 1633, at (703) 308-0447. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-7401. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633.

Janet M. Kerr, Ph.D.
Patent Examiner
Group 1600

DEBORAH J. CLARK
PATENT EXAMINER

Application No.:09/245,198

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- [X] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.
- [X] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- [X] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- [ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- [ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- [ ] 7. Other: the topology of the sequence was not reported.

Applicant Must Provide:

- [X] An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- [X] An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- [X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
For PatentIn software help, call (703) 308-6856

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR RESPONSE